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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

Date of Application: December 22, 2008

APPLICANT: TREU-INSTRUMENTE GMBH
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Device Name Treu Bone Fixation Screws and Pins

Trade Name	Common Name	Product Code	Medical Speciality	Regulation Number	Device Class
Treu Cortical Screws	Screw, Fixation Bone	HWC	87/ Orthopedic	888.3040	2
Treu Corticalis Screws	Screw, Fixation Bone	HWC	87/ Orthopedic	888.3040	2
Treu Shank Screws	Screw, Fixation Bone	HWC	87/ Orthopedic	888.3040	2
Treu Cancellous Screws	Screw, Fixation Bone	HWC	87/ Orthopedic	888.3040	2
Treu Compression Screws	Screw, Fixation Bone	HWC	87/ Orthopedic	888.3040	2
Treu Snap off Screws	Screw, Fixation Bone	HWC	87/ Orthopedic	888.3040	2
Treu Cannulated Screws	Screw, Fixation Bone	HWC	87/ Orthopedic	888.3040	2
Treu Schanz Screws	Pin, Fixation, Smooth	JDW	87/ Orthopedic	888.3040	2
Treu SpiRe Schanz Screws	Pin, Fixation, Smooth	JDW	87/ Orthopedic	888.3040	2
Treu Kirschner Wires	Pin, Fixation, Smooth or Threaded	HTY / JDW	87/ Orthopedic	888.3040	2
Treu Larsen Pins	Pin, Fixation, Smooth	HTY	87/ Orthopedic	888.3040	2
Treu Steinmann Pins	Pin, Fixation, Smooth	JDW	87/ Orthopedic	888.3040	2

Description of the Device

Treu Bone Screws are available in thread diameters ranging from ø1.5 mm to ø7 mm, lengths ranging from 6 mm to 130 mm, are either cannulated or non-cannulated and made of stainless steel or titanium alloy.

Treu Schanz Screws are available in wire diameters ranging from ø3.0 mm to ø6.0 mm, lengths ranging from 60 mm to 350 mm, thread lengths ranging from 20 mm to 50 mm and are made of stainless steel.

Treu Kirschner Wires are available in wire diameters ranging from ø0.8 mm to ø3.0 mm, lengths ranging from 70 mm to 500 mm, are partially or completely smooth or threaded and are made of stainless steel.

Treu Steinmann Pins are available in wire diameters ranging from ø3.0 mm to ø6.0 mm, lengths ranging from 80 mm to 500 mm, are partially or completely smooth or threaded and are made of stainless steel.

Treu Larsen Pins are available in one diameter (ø1.6 mm) and four lengths (60, 80, 100, 120 mm). The head of the pin is 2.5 mm thick and the anchoring hole is ø1.2 mm to facilitate a ø1 mm

cerclage wire. The proximal part of the Larsen Pin is prepared for cutting and fits in conventional as well as mini drivers.

Intended Use

The Treu Bone Fixation Screws and Pins are intended to be used as implants for the fixation of bone fractures, fusion of joints or bone reconstructions or as guide pins for insertion of other implants.

Substantial Equivalence

Treu Bone Fixation Screws and Pins are substantial equivalent to the predicate devices of Stryker Osteonics K983006, Synthes (USA) K021932, Darco International, Inc. K062103, DePuy Orthopedics Inc. K062352, Synthes (USA) K002605, OsteoMed L.P. K063298, Störk Instrumente GmbH K030665, OsteoMed (USA) K062863, Stryker Traum [formal:Howmedica Osteonics Corp (USA)] K000080.

Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that TREU-INSTRUMENTE Bone Fixation Screws and Pins are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

TREU-INSTRUMENTE GmbH
% MEDAGENT GmbH & Co. KG
Mr. Franz Menean
Griesweg 47
Mühlheim, Baden-Württemberg
GERMANY 78570

JUL 15 2009

Re: K083912
Trade/Device Name: Treu Bone Fixation Screws and Pins
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, JDW, HTY
Dated: July 14, 2009
Received: July 14, 2009

Dear Mr. Menean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K083912**

Device Name:

Treu Bone Fixation Screws and Pins

Indications for Use:

The Treu Bone Fixation Screws and Pins are intended to be used as implants for the fixation of bone fractures, fusion of joints or bone reconstructions or as guide pins for insertion of other implants.

Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083912